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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,710

02/24/2004

Mark L. Nelson

16534-512C01US

3651

30623

7590

12/08/2009

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EXAMINER

HAVLIN, ROBERT H

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

12/08/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/786,710	Applicant(s) NELSON ET AL.	
	Examiner ROBERT HAVLIN	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,7,11,23-25,32 and 67 is/are rejected.
- 7) ☒ Claim(s) 4,6,9,10,13,14,19,21,82,103,109 and 110 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/18/09</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims pending in the application are 1, 4, 6-7, 9-11, 13, 14, 19, 21, 23-26, 30, 32, 34-40, 56-65, 67, 68, 82, 103-112, 117-143, 145-147, and 149-158.

Continuation of Disposition of Claims: Claims withdrawn from consideration are 14,25,26,30,34-40,56-65,67,68,104-108,111,112,117-143,145-147 and 149-158.

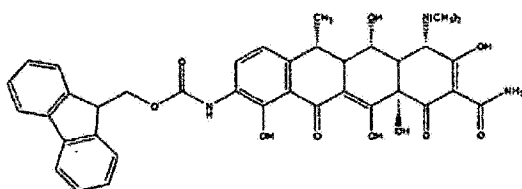
DETAILED ACTION

Status of the claims: Claims 1, 4, 6-7, 9-11, 13, 14, 19, 21, 23-26, 30, 32, 34-40, 56-65, 67, 68, 82 and 103-112, 117-143, 145-147, and 149-158 are pending in the application.

Election / Restriction

The elected group and species is cited from the office action of 1/5/2006:

Acknowledgement is made of Applicant's election (without traverse) of Group I
and, for search purposes, the species,



, in a response filed 11/09/2005.

As detailed in the rejection below, no generic claim was found patentable; therefore, the claims remain restricted in scope to the elected species only. Subject matter reading outside the scope of the elected species is hereby withdrawn.

Claims 1, 4, 6-7, 9-11, 13, 19, 21, 23-24, 32, 82, 103, 109, and 110 read on the elected species. Therefore claims 14, 25, 26, 30, 34-40, 56-65, 67, 68, 104-108, 111, 112, 117-143, 145-147, and 149-158 not reading on the elected species are withdrawn from consideration.

RESPONSE TO APPLICANT REMARKS

Double patenting

The double patenting rejections of claims 1, 4, 6-7, 9-11, 13, 14, 19, 21, 23, 24, 30, 32, 34-40, 82, and 140-143, 145-147, and 149-154 over 10/839023 is **withdrawn**. The definition of R9 in the applications substantially differ.

Claim Rejections - 35 USC § 103

1. Claims 1, 7, 11, 23-25, and 67 were rejected under 35 U.S.C. 103(a) as being unpatentable over Barden et al. (J. Med Chem, 1994, v. 37, no. 20, p. 3205-3211) in view of Silverman, R. B. (The Org. Chem. of Drug Design and Drug Action, Academic Press, Inc.: San Diego, 1992, pp. 4-51).

First, applicant argues that Barden's compound 12 exhibits no antibacterial activity against gram negative bacteria. The examiner responds by noting that table 1 of Barden shows compound 12 as having antibacterial activity towards S. aureus and indicates ">32" with respect to E. coli activity. Regardless, Barden teaches compound 12 as being one of the most effective compounds for S. aureus and would suggest it as a candidate for optimization.

Next, applicant excerpts *Eisai v. Dr. Reddy* and containing the language with respect to obviousness: "it is sufficient to show that the claimed and prior art compounds possess a 'sufficiently close relationship . . . to create an expectation,' in light of the totality of the prior art, that the new compound will have 'similar properties' to the old." In response, the examiner points to the teaching in Barden of the activity of compound 12 and the suggestion that alkyl homologs also possessed antibacterial activity. Therefore, the totality of the prior art leads to the conclusion that alkyl

homologs of compound 12 will have similar properties. Thus, this supports the conclusion of obviousness.

Applicant again refers to alleged “superior properties” (on page 19) of the claimed compounds relative to the compounds of Barden. But this is not persuasive because one of ordinary skill in the art would arrive at the claimed invention based on the teaching of Barden alone. If applicant is attempting to establish an unexpected result, the argument is not persuasive because one of ordinary skill in the art would expect the compound to have some antibacterial activity even for *E. coli* as was indicated by “>32” in Barden’s table 1.

Next, applicant argues that Barden does not suggest the modification of compound 12 and Silverman does not cure the deficiencies of Barden. As discussed above, by Barden, and in the prior office action, alkyl homologs are reasonably expected to possess the similar activity. This was reiterated in *Eisai* and is stated in the MPEP. Nothing of record tends to show the compounds claimed here are an exception to this expectation.

Thus, none of applicant's arguments are persuasive and the rejection is **maintained**.

Claim Rejections - 35 USC § 112

2. Claims 1, 4, 6-7, 9-11, 13, 19, 21, 23-24, 32, and 82 were rejected under 35 USC 112 1st paragraph as failing to comply with the written description requirement.

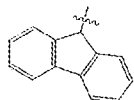
With respect to the scope of R9a, applicant amended C3-C10 alkyl to specifically recite the alkyl groups found in the specification. Thus, this aspect of the rejection is **withdrawn**.

3. The amended claim 32 was previously rejected as creating an unsupported new

subgenus with the amendment: .

Applicant again argues that the following disclosure in the specification provides support for the amendment:

- aryl and heteroaryl. In certain embodiments, the substituents are alkoxy, carbonyl, amino, aryl, carbonyl, halogen, hydroxy, alkylamino, alkoxy, or aryl. In certain embodiments, the substituent is halogen (*e.g.*, bromine, chlorine, iodine, fluorine).
- 15 In a further embodiment, R^{9a} includes at least one aryl group, *e.g.*, heteroaryl, phenyl, naphthyl, fluorene, *etc.* Fluorene is a moiety of the formula:



- 15 In one embodiment, R^{9a} is aryl, *e.g.*, substituted or unsubstituted phenyl. Examples of substituents include, but are not limited to, alkyl (*e.g.*, unsubstituted, *e.g.*, methyl, ethyl, propyl, butyl, or substituted, *e.g.*, chloromethyl, dichloromethyl, perchloromethyl, fluoromethyl, difluoromethyl, perfluoromethyl, *etc.*), alkenyl, alkynyl, aryl, alkoxy (*e.g.*, methoxy, ethoxy, propoxy, *etc.*), aryloxy, alkylcarbonyl, arylcarbonyl, alkoxy, carbonyl, aryloxy, carbonyl, amide, halogen, nitro, azo, alkyl sulfonyl, and arylsulfonyl.

as well as p. 10 lines 12 and 17 and the two compounds A and AT from table 2.

This support is insufficient because there is no specific recitation of such subject matter, only a generic description that does not demonstrate that applicants had possession. Again, with over a million compounds, applicant fails to show a substantial disclosure of representative species to demonstrate possession of such a new subgenus with the broad definitions of the other variables as discussed above.

For the above reasons, the rejection is **maintained**.

Claim Rejections - 35 USC § 112

4. Claims 1-4, 6-7, 9-13, 19, 21, 23-24, 32, 82 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement because claims

used definitions for variables including “a prodrug moiety.” Applicant has deleted the phrase from the claims, thus the rejection is **withdrawn**.

Claim Objections

5. Claims 4,6,9,10,13,14,19,21,82,103,109 and 110 are objected to for being dependent on a rejected base claim or reading on subject matter beyond of the restricted scope of the elected species.

Conclusion

The claims are not in condition for allowance. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action. The claims are not in condition for allowance.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is

Art Unit: 1626

(571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Examiner, Art Unit 1626

/Rebecca L Anderson/
Primary Examiner, Art Unit 1626